

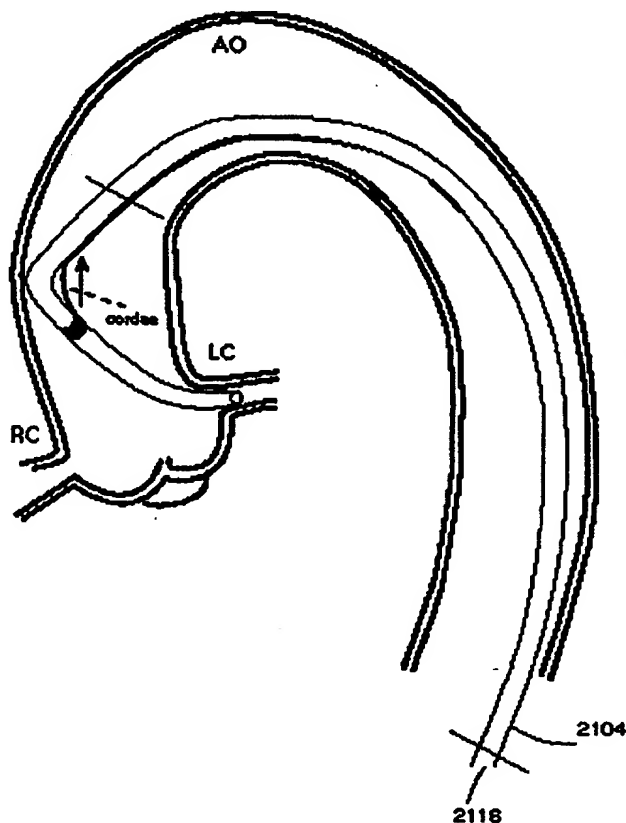
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(71) Applicant (for all designated States except US): CONDADO MEDICAL DEVICES CORPORATION [US/US]; c/o National Registered Agents, Inc., Suite 300, 1295 Bandana Boulevard North, St. Paul, MN 55108-5116 (US).		Date of publication of the amended claims: 12 November 1998 (12.11.98)	
(72) Inventor; and			
(75) Inventor/Applicant (for US only): CONDADO, Jose Antonio R. [-/VE]; Conjunto res. Chamonix, Torre Norte, Piso 7, Apartamento 13B, Calle Julio Urbano, Sebugan, Caracas 1071 (VE).			
(74) Agents: NOTO, Aldo et al.; Dorsey & Whitney LLP, Suite 200, 1330 Connecticut Avenue, N.W., Washington, DC 20036 (US).			

(54) Title: MULTI-PURPOSE CATHETERS, CATHETER SYSTEMS, AND RADIATION TREATMENT

(57) Abstract

This invention is new apparatuses and methods for treatments to be used from inside conduits or biological pathways. Examples of the biological pathways in which these new apparatuses and methods may be used include arteries, veins, and respiratory ways. Multi-purpose catheters (10) and catheter systems using structures including wires (2108), balloons (2150), and cords (2204) are described as well as methods to use such catheters and catheter systems. One of the embodiments is a configurable wire system which carries or transports radioactive sources. The wire is used in conjunction with a closed-end channel catheter.



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AMENDED CLAIMS

[received by the International Bureau on 30 September 1998 (30.09.98);
original claims 1, 22, 38, 41, 42, 44, 45, 47-49, 53-56, 61, 69-75, 78-81, 86, 87,
93, 105, 106, 113 and 116-119 amended; remaining claims unchanged (12 pages)]

1. A catheter assembly, comprising:
 - (a) a flexible tubular catheter body having an inner lumen;
- 5 and
 - (b) at least one fluid communication structure formed on the catheter body, the at least one fluid communication structure adapted to permit fluid flow through a biological path.
2. The catheter of claim 1, wherein each fluid communication
- 10 structure comprises:
 - (a) at least one bulk formed on the catheter body; and
 - (b) at least one conduit formed on the bulk, wherein the at least one conduit is adapted to permit fluid flow through a biological path.
- 15 3. The catheter of claim 2, wherein a radiating source is disposed within the inner lumen.
4. The catheter of claim 2, wherein the catheter has a plurality of bulks on the catheter body.
5. The catheter of claim 4, wherein each bulk has a length, the
- 20 length of each bulk being approximately three to seven millimeters.
6. The catheter of claim 1, further comprising at least one marker attached to the catheter body, wherein the marker enables a user to position a radiating source within a biological path.
- 25 7. The catheter of claim 2, further comprising at least one balloon attached to a distal end of the outer surface of the catheter body.
8. The catheter of claim 7, wherein the at least one balloon extends over the at least one bulk.

14. A catheter for use in biological paths to provide fluids and/or gases perfusion across the entire catheter when inserted in a biological path, wherein the catheter comprises two or more concentric or non concentric conduits and one or more balloons attached to most exterior conduit; the more interior conduit used for placing devices used in catheter operations; the exterior channel for providing a track for fluids and/or gases without substantially obstructing fluid flow through the biological paths.
15. A catheter according to claim 13 or 14, where the exterior conduit permits positioning a radiation and/or radioactive source at a desirable distance from the biological paths.
16. A catheter according to claim 13 or 14, where the exterior conduit supports the walls of the biological paths.
17. A catheter according to claim 13 or 14, where the exterior conduit is of flexible material.
18. A catheter according to claim 13 or 14, where the exterior conduit prolongate along the entire length of the interior conduit.
19. A catheter according to claim 13 or 14, where the exterior conduit are segments of conduits located along the entire length and/or at specific locations of the interior channel.
20. A catheter according to claim 13 or 14, where the exterior conduit have perpendicular to its cross section micro-conduits and/or pores.
21. A catheter according to claim 20, where the cross section of the micro-conduits and/or pores are parallelepites of regular or irregular shape.
22. A catheter according to claim 21, where the cross section of the micro-conduits and/or pores are circles, ellipses and/or rectangles.

34. A catheter according to claim 14, where the balloons are located at specific locations along the entire length of the exterior conduit.

5 35. A catheter according to claim 13 or 14, where said external conduits having on its outer surface pores which extend from said outer surface to the above mentioned micro-conduits, being said pores oriented at whatever desired angle with respect to the micro-conduits.

10 36. The catheter of claim 19, wherein the segments and the space between the segments are covered by a membrane.

37. The catheter of claim 27, wherein the open channels are covered by a membrane.

38. The catheter of any one of claims 1 to 14 wherein the catheter includes a valve.

15 39. The catheter of claim 38 wherein the valve is a U-shaped metallic valve built into a lumen or channel of the catheter.

40. The catheter of claim 38 wherein the catheter has multiple valves.

20 41. The catheter of any one of claims 1 to 14 wherein the catheter further comprises a pressure monitor or a blood pressure monitor.

42. The catheter of any one of claims 1 to 14 wherein the catheter further comprises a marker.

25 43. The catheter of claim 42 wherein the marker is for visually marking the catheter with visual monitoring equipment.

44. The catheter of any one of claims 1 to 14 further comprising a stent or membrane for maintaining a cell wall.

45. The catheter of any one of claims 1 to 14 further comprising a guide wire.

46. The catheter of claim 45 further comprising a second guidewire, wherein at least one of the guidewires is made of nickel alloy.

5 47. The catheter of any one of claims 1 to 14 further comprising an over-the-wire guidewire.

48. The catheter of any one of claims 1 to 14 wherein an automatic radiating source placement machine is used with the catheter and wherein the radiating source is made of iridium or strontium.

10 49. The catheter of any one of claims 1 to 14 wherein a guidewire may be removed from the catheter and another wire placed into the catheter.

50. A method for using a medical procedure comprising the following steps:

15 a guide wire is placed into a biological path and beyond the place where treatment is to occur;

a catheter is placed into the biological path using a rail system attached to the distal end of the closed channel;

20 when the fluid communication structure is placed in the area to be treated the balloon is inflated;

the guide wire is then removed and an irradiation source is placed in the closed channel or inner lumen;

25 the irradiation source may be attached to the distal end of a metallic wire or other different irradiation source systems utilized.

51. The method of claim 50 wherein

a second guide wire is placed in the closed channel formed in the inner lumen to assist the introduction of the catheter in the biological path.

52. The method of claim 50 or 51 wherein an over-the-wire, monorail, or multiple wire, techniques is used for insertion of the catheter.

53. The method of claim 50 or 51, wherein an irradiation source is placed in the inner lumen and a guide wire may be used to move the irradiation source to the distal end or near the distal end of the closed channel of the inner lumen using an automatic machine to move the irradiation source to the distal end of the channel.

54. The method of claim 50 or 51, wherein once the catheter body is in place at the biological path, the perfusion holes and allow fluids or gases to flow through the catheter body, thereby preventing an occlusion at the biological path where treatment is occurring.

55. The method of claim 50 or 51, wherein depending on whether the irradiation source needs to be centered a catheter having an appropriate fluid communication structure may be chosen.

56. The method of claim 50 or 51, wherein further comprising the steps of:

removing the guidewire.

57. A catheter for infusing drugs to a localized area of the wall of a biological path comprising:

means for generating a trap against the wall; and

means for infusing a drug into the trap.

58. The catheter of claim 57 wherein the means for generating a trap comprises a balloon.

59. The catheter of claim 57 or 58 wherein the means for generating a trap comprises a transverse wavy balloon.

60. The catheter of claim 57 or 58 wherein the means for generating a trap comprises a two ring shaped balloons.

61. The catheter of claim 57 or 58, wherein means for infusing drugs comprises an infusion port.

5 62. A method for infusing drugs using a catheter comprising the steps of:

creating a trap against a wall of a biological path; and
providing the drug to the created trap.

10 63. The method of claim 62 wherein the step of creating the trap comprises:

inflating a balloon.

64. The method of claim 62 or 63 wherein the step of providing the drug comprises dispensing the drug under pressure through an infusion port.

15 65. A method for centering a lumen in a two lumen catheter comprising:

inflating balloons positioned to center one lumen and
displace the second lumen wherein the second lumen is not
centered.

20 66. A system for medical procedures to be used in biological pathways comprising:

an inflator tube for inflating other tubes;

at least one inflatable tube operably connected to the inflator tube
which can be inflated by the inflator tube while in a biological pathway;

25 a form, connected to the inflator tube and at least one inflatable
tube, wherein the form maintains or assists in maintaining the relative
position of the inflator tube to at least one inflatable tube.

67. The system of claim 66, wherein the system is attached to a catheter.

68. The system of claim 66 or 67 wherein the system further comprises two ends an entry end and a distal end; and

5 wherein the system slides onto a catheter, wherein the catheter may pass from the entry end through the system to the distal end.

69. The system of claim 66 or 67, wherein the system further comprises a catheter, whereby the catheter may be slid through
10 the other components of the system while the system is deployed in a biological pathway.

70. The system of claim 66 or 67, wherein the catheter is inside one tube, either the inflator tube or one of the inflatable tubes.

71. The system of claim 66 or 67, wherein the form comprises
15 a body and a series arms; and

 wherein each arm fits into or slides into a tube, and wherein the body fits into either the inflator tube, the entry end, or the distal end of the system.

72. The system of claim 66 or 67, wherein the system has two,
20 three, four, five six, or seven inflatable tubes, and wherein each inflatable tube has two ends and each end is directly or indirectly connected to the inflator tube.

73. The system of claim 66 or 67, wherein the inflator tube comprises one or more micropores wherein the micropores are
25 used to inflate one or more inflatable tubes, whereby one or more micropores are used to inflate each inflatable tube.

74. The system of claim 66 or 67, wherein the inflator tube comprises openings or passageways in which the form is positioned or passes through the opening or passageway.

75. The system of claim 66 or 67 used in a biological pathways with walls, wherein the inflator tube comprises an entry end and a distal end, and whereby the inflator tubes and the inflatable tubes are generally parallel to each other and to the walls of the biological pathway.

76. A method for guiding a catheter to a coronary artery and around curves or bends in the artery comprising:

guiding a guiding catheter to the vicinity of a coronary artery;
inserting a preformed coronary wire into the catheter;
10 guiding the guiding catheter around or passed the curve or bend in the coronary artery.

77. The method of claim 76 wherein the step of guiding the guiding catheter to the artery is performed with a guide wire.

78. The method of claim 76 or 77, further comprising the steps of:
15 removing the guidewire from the guiding catheter.

79. The method of claim 76 or 77 further comprising the step of:
replacing the guidewire from the catheter with the preformed coronary wire.

20 80. The method of claim 76 or 77, wherein the coronary artery is the left coronary artery and the curve or bend is the the aorta arch of the left coronary artery and the preformed coronary wire is a preformed left coronary wire.

25 81. The method of claim 76 or 77, wherein the coronary artery is the right coronary artery and the curve or bend is the entrance of the right coronary artery and the preformed coronary wire is a preformed right coronary wire.

82. A balloon for changing the flexion of a catheter comprising:
an inflatable balloon attached to a catheter near its distal end,

wherein the balloon is longer in the longitudinal direction and is attached to the catheter in a longitudinal direction and

whereby inflating the balloon changes the flexion of the catheter primarily in its longitudinal direction so that the inflating
5 and deflating of the balloon assists in guiding the catheter through a passageway.

83. A system for changing the flexion of a catheter having a length comprising:

a membrane, connected at two different longitudinal
10 positions along the length of the catheter;

an inflatable balloon, situated between the membrane and the catheter and inbetween the two longitudinal positions; whereby if the balloon is inflated the catheter flexion is changed.

84. The system of claim 83 wherein the length of the membrane
15 between the two longitudinal positions is equal to or longer than the distance between the two longitudinal positions, whereby inflating the balloon causes the membrane to pull the two longitudinal positions closer together causing the catheter to flex.

85. The system of claims 83 or 84 wherein the balloon is
20 attached either to the membrane or to the catheter, wherein the balloon is positioned between the outer wall of the catheter and the inner wall of the membrane.

86. The system of claim 83 or 84, wherein the membrane has a
25 resting state, and wherein the inflated balloon engages the membrane and distorts or changes the shape of the membrane from its resting state prior to engagement.

87. The system of claim 83 or 84, wherein the two longitudinal
30 positions are radially in the same radial location or measurement on the catheter so that the catheter does not twist when the balloon is inflated.

88. A system for changing the flex of a catheter during use of the catheter in a biological pathway comprising:

an object, connected to a catheter with two active locations, wherein placing pressure on the object by engaging or pulling the object causes the catheter to flex in the vicinity of the two active locations.

89. The system of claim 88 wherein the object is engaged or pulled and the distance between the two active locations is shortened or lessened.

90. The system of 88 or 89 wherein the object is a membrane, the membrane is attached at the two active locations to the catheter, and the membrane is engaged.

91. The system of 88 or 89 wherein the object is a cord, the cord runs most of the length of the catheter and whereby, when the cord is engaged or pulled, the cord applies a tension between the two active locations.

92. The system of claim 91 wherein the cord runs most of the length of the catheter inside a conduit, lumen or rail of the catheter.

93. The system of claim 89, wherein there are more than two active locations on the catheter.

94. A method for flexing a catheter during the process of guiding a catheter in a biological pathway, comprising:

placing the catheter in the biological pathway;
guiding the catheter to a curved area of the biological pathway;

engaging or pulling an object which is connected or makes contact with the catheter in at least two locations;

whereby the engaging or pulling of the object causes the catheter to flex in the general area of the at least two locations and

103. The wire of claim 101, or 102 wherein one of the radioactive parts is a stopper.
104. The wire of claim 101, or 102 wherein the radioactive parts are one or more of the following: cylinder, washer, coil, stopper.
- 5 105. The wire of claim 101 or 102, wherein the stud is connected to the drive cable by a weld.
106. The wire of claim 101 or 102, wherein the drive cable is formed from metal and wherein the stud is formed from same metal cable as the drive cable.
- 10 107. A radioactive wire for use in a medical procedure comprising:
a first portion which is substantially or completely non-radioactive; and
a second portion which is radioactive wherein the second portion is configurably connected to the first portion.
- 15 108. The radioactive wire of claim 107 wherein the second portion is configurably connected to the first portion by a push-in connection.
109. The radioactive wire of claim 108 wherein the push-in connection is permanent connection.
- 20 110. The radioactive wire of claim 107, or 108 wherein the connection is a slot connection.
111. The radioactive wire of claim 107 wherein the second portion is made of interchangeable radioactive parts.
112. The radioactive wire of claim 111 wherein the
25 interchangeable radioactive parts are made up of one or more of the following: cylinder, donut, washer, coil, lockable stopper.
113. The radioactive wire of claim 107, 111, or 112 wherein the first portion comprises a stud.

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114. The radioactive wire of claim 107 wherein the second portion is made of one or more radioactive donuts which are placed on the stud.

5 115. The radioactive wire of claim 114 wherein the radioactive donuts are locked in place on the stud.

116. The radioactive wire of claim 107, 108, 109, 111, 112, 114, or 115 wherein the radioactive wire is placed in a catheter.

10 117. The radioactive wire of claim 107, 108, 109, 111, 112, 114, or 115 wherein the radioactive portion has a length of between 3mm and 30mm.

118. The radioactive wire of claim 107, 108, 109, 111, 112, 114, or 115 wherein the radioactive portion has a diameter of between .33mm and 1mm.

15 119. The radioactive wire of claim 107, 108, 109, 111, 112, 114, or 115 wherein the radioactive portion has a lockable stopper.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US98/03178

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61M 25/00

US CL : 604/280

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/3-5; 604/49, 96-102, 280

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,503,613 A (WEINBERGER) 02 April 1996, Abstract.	1-3, 6, 7, 10, 11, 13-34, 76-78, 82
X	US 4,883,459 A (CALDERON) 28 November 1989, Abstract.	1-4
X	US 5,282,781 A (LIPRIE) 01 February 1994, Abstract.	95, 96, 101, 102, 107-110, 112, 113
A	US 4,861,520 A (VAN'T HOOFT et al.) 29 August 1989, Abstract.	1-37, 50-52, 57- 60, 62-68, 76-78, 82-85, 88-92, 94- 115



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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Date of the actual completion of the international search

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Authorized officer

DEBORAH BLYVEIS

Facsimile No. (703) 305-3230

Telephone No. (703) 308-2110

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/03178

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 38-49, 53-56, 61, 69-75, 79-81, 86-87, 93, 116-119
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

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